

Peri-Strips Dry

Circular Staple Line Reinforcement With VERITAS Collagen Matrix

INSTRUCTIONS FOR USE

PERI-STRIPS DRY Circular Staple Line Reinforcement with VERITAS Collagen Matrix
Figures 1-6

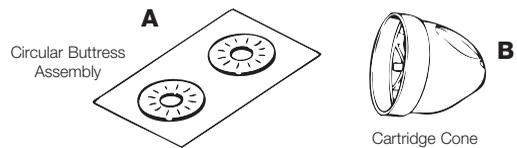


FIGURE 1

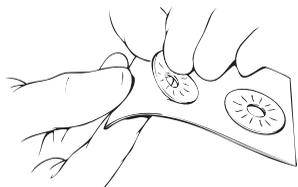


FIGURE 2

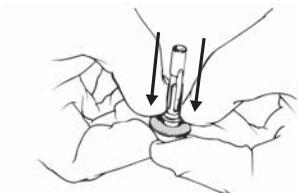


FIGURE 3



FIGURE 4

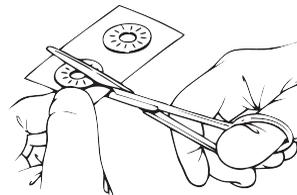


FIGURE 5

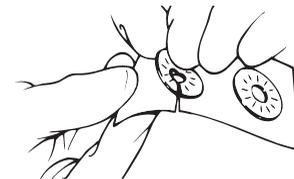


FIGURE 6

PERI-STRIPS DRY Circular Staple Line Reinforcement with VERITAS Collagen Matrix
Figures 7-11

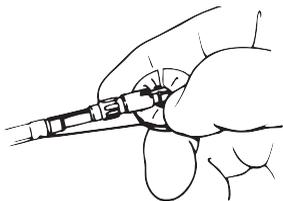


FIGURE 7

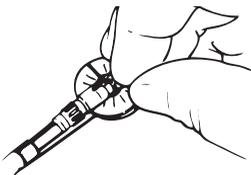


FIGURE 8



FIGURE 9

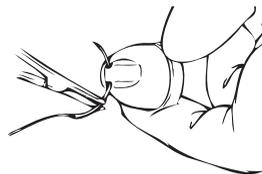


FIGURE 10

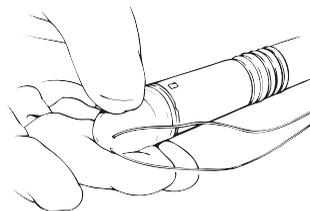


FIGURE 11

A
Circular Buttress Assembly



B
Cartridge Cone

Symbols Referenced on Labeling

Symbol Glossary per US FD&C Act:

Standard*	Symbol	Symbol Title	Symbol Meaning	Symbol Number
ISO 15223-1		Manufacturer	Manufacturer	5.1.1
ISO 15223-1		Use-by date	Use-by date	5.1.4
ISO 15223-1		Batch code	Lot number	5.1.5
ISO 15223-1		Catalogue number	Catalog number	5.1.6
ISO 15223-1		Sterilized using ethylene oxide	Sterilized using ethylene oxide	5.2.3
ISO 15223-1		Do not re-sterilize	Do not re-sterilize	5.2.6
ISO 15223-1		Do not use if package is damaged	Do not use if the product sterile barrier or its packaging is compromised	5.2.8
ISO 15223-1		Keep away from sunlight	Keep away from heat. Do not use if heat indicator is red	5.3.2
ISO 15223-1		Temperature limit	Store at controlled room temperature	5.3.7
ISO 15223-1		Do not re-use	Do not re-use	5.4.2
ISO 15223-1		Consult instructions for use	Consult instructions for use	5.4.3
ISO 15223-1		Caution	Caution: Consult instruction for use for warning and precaution information	5.4.4
			Content	
			Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	

*ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.

Additional symbols on the product labeling that are not required by the US FD&C Act:

Symbol	Symbol Meaning
	Made in the U.S.A.
	Manufacturer internal code
	Manufacturer part number
	Manufacturer tracking number
	This product is derived from cattle

DESCRIPTION:

PERI-STRIPS DRY Circular Staple Line Reinforcement with VERITAS Collagen Matrix (PSDV-C) is prepared from dehydrated bovine pericardium procured from cattle under 30 months of age in the United States.

The packaging contains a buttress assembly which includes two (2) circular buttresses, one for the anvil and one for the cartridge side of the stapler. Each buttress assembly has a coating of acrylic adhesive on one side for attachment to the stapler surfaces. The packaging also includes one cartridge cone to aid atraumatic advancement of the stapler into the surgical site. All components are packaged sterile.

PSDV-C utilizes animal tissue; patient must be informed prior to any procedure. See Table 1 for product models and configurations.

Table 1 PSDV-C Model Numbers and Sizes

Model Number	Size
PSD 21-V	21 mm
PSD 25-V	25 mm

INDICATIONS FOR USE:

PSDV-C is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed.

PSDV-C can be used for reinforcement of staple lines during gastric, bariatric, and small bowel procedures.

CONTRAINDICATIONS:

The use of PSDV-C is contraindicated in patients with known sensitivity to bovine or acrylic material.

ADVERSE REACTIONS:

As with any surgical procedure involving implantation of a foreign material, adverse reactions are possible and include but are not limited to: infection, rejection, erosion, and allergic reaction.

WARNINGS:

Do not re-sterilize. Resterilization may cause changes to the tissue and negatively impact functionality of the device.

Discard all open, used or unused components as sterility is no longer assured.

Do not use product if there is damage to the pouch or seals as sterility may be compromised.

Ensure the staple line is completely covered with the buttress or inadequate coverage after firing may result.

PSDV-C is not designed, sold, or intended for use except as indicated; doing so may result in surgical complications.

Synovis products differ; substitution of one product for another product may reduce product performance.

Do not use PSDV-C if heat indicator on the carton label has been activated (i.e. turns red).

CAUTIONS:

Do not get the anvil or cartridge buttress wet before applying, or the buttress may not adhere to the stapler properly.

Cartridge cones may be used for entry into the surgical site on the cartridge side of the stapler during endoscopic surgery. Before completion of surgery be sure to remove the cartridge cone from the surgical site.

Final tissue compression, including PSDV-C, must meet the range specified by the stapler manufacturer. PSDV-C increases the total thickness of the area stapled by 0.4 mm - 1.2 mm (0.016" - 0.048").

Follow *Instructions for Use* supplied by the stapler manufacturer. Do not use PSDV-C contrary to the stapler manufacturer's instructions.

PSDV-C COMPONENTS:

Each PSDV-C package contains the following components (See Figure 1): A) one (1) pouch containing a circular buttress assembly which includes two (2) circular buttresses and B) one (1) pouch containing a cartridge cone.

Cartridge cone (See B): The cartridge cone is designed to protect the cartridge buttress during advancement of the stapler into the surgical site. There are two features to facilitate removal of the cone from the stapler and from the surgical site before completion of the surgery: 1. the indentations at the top of the cone are designed to

allow the use of a forceps/hemostat to remove the cone from the stapler and/or surgical site, 2. the holes at the tip of the cartridge cone are designed to allow a suture to be placed in the cone to facilitate the removal of the cone from the surgical site.

INSTRUCTIONS FOR USE:

Each model of PSDV-C has been designed specifically for the stapler models indicated on the label; verify that the correct model of PSDV-C has been selected. Buttress Assemblies are identical and can be used on either the anvil or cartridge of the stapler.

Do not allow the buttresses, anvil, or cartridge surface to become wet. A wet buttress or a wet stapler surface may affect the ability of the buttress to adhere to the stapler surface.

Instructions for 21 mm or 25 mm circular staplers (Ethicon Endo-Surgery, Inc. and Covidien Autosuture):

A. Product Preparation

- A. Inspect the carton. Do not use PSDV-C if the heat indicator has been activated.
- B. Remove the pouches from the carton.
- C. Inspect the pouch(s). Do not use if any pouch is damaged or if the seal is not intact.
- D. Peel open the outer pouch of the buttress assembly and aseptically remove the inner pouch. The inner pouch may be placed in the sterile field.
- E. Peel open the pouch containing the cartridge cone and aseptically deliver the cone to the sterile field.

B1. Anvil Preparation

- F. Open inner pouch and remove the buttress assembly.
- G. Grasping the backing, peel away a single circular buttress (See Figure 2).
- H. Place the buttress over the anvil shaft with the adhesive side down towards the anvil surface (See Figure 3).
- I. Slide the buttress down the shaft of the anvil. The fit will be snug, use pressure to slide the buttress down the shaft.

J. Press the buttress onto the surface of the anvil, ensuring that the buttress is centered and covers all staples and that there are no gaps between the buttress and the surface of the anvil (See Figure 4). Failure to ensure the staple line is completely covered with the buttress may result in inadequate coverage after firing.

B2. Anvil Preparation for the Orvil Anvil Introducer

- K. Open inner pouch and remove a buttress assembly.
- L. Create a slit in one of the circular buttresses by cutting completely through one side of the buttress to the center hole (See Figure 5).
- M. Grasp the backing and peel away the cut buttress from the backing (See Figure 6).
- N. With the adhesive side down towards the anvil surface, slide the cut edge of the buttress over the shaft of the anvil (See Figure 7).
- O. Press the buttress onto the surface of the anvil, ensuring that the buttress is centered and covers all staples and that there are no gaps between the buttress and the surface of the anvil (See Figure 8). Failure to ensure the staple line is completely covered with the buttress may result in inadequate coverage after firing. Ensure that there is no gap at the slit.
Note: Ensure proper alignment before applying pressure to the buttress.

C. Cartridge Preparation

- A. Grasping the backing, peel away a single buttress. (See Figure 2).
- B. Press the buttress onto the surface of the cartridge with the adhesive side down ensuring that the buttress is centered and covers all staples, and that there are no gaps between the buttress and the surface of the cartridge (See Figure 9). Failure to ensure the staple line is completely covered with the buttress may result in inadequate coverage after firing.

D. Buttress Hydration

- A. After applying buttresses to anvil and cartridge, immerse buttresses in sterile water or sterile saline for approximately 5 seconds.

E. Cartridge Cone Preparation and Application

- A. The tip of the cone contains several holes through which a suture may be placed.
 - B. Loop and tie a suture through two of the holes of the cone leaving a length of suture equal to or greater than the length of the stapler (approximately 15 inches, or 38cm) (See Figure 10).
- Note: The recommended suture is an absorbable or non-absorbable material containing no memory for shape, e.g. silk, attached to a 2-0 curved needle.
- C. Press the cone over the end of the stapler cartridge (See Figure 11).

IMPLANTING PSDV-C INSTRUCTIONS FOR ALL STAPLER MODELS:

- A. After inserting the stapler into the surgical site, remove the cartridge cone from the stapler by advancing the inner shaft or using a forceps/hemostat to grasp the tip of the cone. Note: If a suture has been placed in the cone, do not grasp or apply tension to the suture while removing the cone.
- B. Follow the stapler manufacturer Instructions For Use to fire and remove the stapler. After firing, removal of the circular stapler through the buttressed anastomosis may be more difficult due to the reinforcement of the staple line.
- C. Before completion of the surgery, remove cartridge cone from the surgical site either by pulling on the suture placed through the tip of the cartridge cone or by grasping with a forceps/hemostat.

Disposal

Any packaging or components exposed to human tissue/fluids should be disposed of per hospital protocols. Any open unused components should be discarded due to compromised sterility.

DISCLAIMER OF WARRANTIES

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